

EXHIBIT A

APPROVED DRUG PRODUCTS with **THERAPEUTIC EQUIVALENCE EVALUATIONS**

The products in this list have been approved under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. This volume and accompanying first supplement are current through January 31, 1997.

17TH EDITION



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DATABASE MANAGEMENT

1997

PRESCRIPTION DRUG PRODUCT LIST

3-134

ETHINYL ESTRADIOL; NORETHINDRONE

AB	TABLET; ORAL-28 BREVICON 28-DAY SEARLE	0.035MG; 0.5MG	N17743 001
AB	GENCEPT 0.5/35-28 GENCON	0.035MG; 0.5MG	N72695 001 FEB 28, 1992
AB	GENCEPT 1/35-28 GENCON	0.035MG; 1MG	N72696 001 FEB 28, 1992
AB	GENCEPT 10/11-28 GENCON	0.035MG, 0.035MG; 0.5MG, 1MG	N72697 001 FEB 28, 1992
AB	MODICON 28 JOHNSON RW	0.035MG; 0.5MG	N17735 001
AB	NORCEPT-E 1/35 28 GYNOFARMA	0.035MG; 1MG	N71546 001 FEB 09, 1989
AB	NORETHIN 1/35E-28 ROBERTS LABS	0.035MG; 1MG	N71481 001 APR 12, 1988
AB	NORETHINDRONE AND ETHINYL ESTRADIOL WATSON LABS	0.035MG; 0.5MG	N70686 001 JAN 29, 1987
AB	NORETHINDRONE AND ETHINYL ESTRADIOL (10/11) WATSON LABS	0.035MG, 0.035MG; 0.5MG, 1MG	N71044 001 APR 01, 1988
AB	NORETHINDRONE AND ETHINYL ESTRADIOL (7/14) WATSON LABS	0.035MG, 0.035MG; 0.5MG, 1MG	N71042 001 SEP 24, 1991
AB	NORINYL 1+35 28-DAY SEARLE	0.035MG; 1MG	N17565 002
AB	ORTHO-NOVUM 1/35-28 JOHNSON RW	0.035MG; 1MG	N17919 002
AB	ORTHO-NOVUM 10/11-28 IN PLASTIC CONTAINER JOHNSON RW	0.035MG, 0.035MG; 0.5MG, 1MG	N18354 002 JAN 11, 1982
AB	ORTHO-NOVUM 7/14-28 + JOHNSON RW	0.035MG, 0.035MG; 0.5MG, 1MG	N19004 002 APR 04, 1984
	ORTHO-NOVUM 7/7/7-28 JOHNSON RW	0.035MG, 0.035MG, 0.035MG; 0.5MG, 0.75MG, 1MG	N18985 002 APR 04, 1984
	OVCON-35 BRISTOL MYERS SQUIBB	0.035MG; 0.4MG	N17716 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28 OVCON-50	BRISTOL MYERS SQUIBB	0.05MG; 1MG	N17576 001
TRI-NORINYL 28-DAY SEARLE		0.035MG, 0.035MG; 0.5MG, 1MG	N18977 002 APR 13, 1984

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-21 ESTROSTEP 21 + PARKE DAVIS		0.02MG, 0.03MG, 0.035MG; 1MG, 1MG, 1MG	N20130 001 OCT 09, 1996
LOESTRIN 21 1.5/30 + PARKE DAVIS		0.03MG; 1.5MG	N17875 001
LOESTRIN 21 1/20 + PARKE DAVIS		0.02MG; 1MG	N17876 001
TABLET; ORAL-28 ESTROSTEP FE + PARKE DAVIS		0.02MG, 0.03MG, 0.035MG; 1MG, 1MG, 1MG	N20130 002 OCT 09, 1996
LOESTRIN FE 1.5/30 + PARKE DAVIS		0.03MG; 1.5MG	N17355 001
LOESTRIN FE 1/20 + PARKE DAVIS		0.02MG; 1MG	N17354 001

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-21 ORTHO CYCLEN-21 + JOHNSON RW		0.035MG; 0.25MG	N19653 001 DEC 29, 1989
ORTHO TRI-CYCLEN + JOHNSON RW		0.035MG, 0.035MG, 0.035MG; 0.18MG, 0.215MG, 0.25MG	N19697 002 JUL 03, 1992
TABLET; ORAL-28 ORTHO CYCLEN-28 JOHNSON RW		0.035MG; 0.25MG	N19653 002 DEC 29, 1989

PRESCRIPTION DRUG PRODUCT LIST

3-132

ESTROPIPATE

TABLET; ORAL
ESTROPIPATE
BARR

AB 0.75MG

AB 1.5MG

AB 3MG

AB 0.75MG

AB 1.5MG

AB 3MG

AB 6MG

AB OGEN .625

AB ABBOTT

AB OGEN 1.25

AB ABBOTT

AB OGEN 2.5

AB ABBOTT

AB OGEN 5

AB ABBOTT

AB ORTHO-EST

AB JOHNSON RW

AB

ETHACRYNATE SODIUM

INJECTABLE; INJECTION
EDECRIN
+ MERCK SHARP DOHME

EQ 50MG BASE/VIAL

ETHACRYNIC ACID

TABLET; ORAL
EDECRIN
MERCK SHARP DOHME
+

25MG
50MG

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL
MYAMBUTOL
LEDERLE
+

100MG
400MG

N16320 001
N16320 003

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION
ETHAMOLIN
+ CYPROS

50MG/ML

N19357 001
DEC 22, 1988

ETHCHLORVYNOL

CAPSULE; ORAL

ETHCHLORVYNOL

AA BANNER PHARMACAPS

200MG
500MG
750MG
100MG

N84463 002
N84463 003
N84463 004
N84463 001

PLACIDYL

AA + ABBOTT

AA +

AA +

200MG
500MG
750MG

N10021 007
N10021 002
N10021 010

ETHINYL ESTRADIOL

TABLET; ORAL
ESTINYL
SCHERING

0.02MG
0.05MG
0.5MG

N05292 001
N05292 002
N05292 003

ETHINYL ESTRADIOL; *MULTIPLE*

SEE DESOGESTREL; ETHINYL ESTRADIOL

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET; ORAL-21

DEMULEN 1/35-21

AB + SEARLE

DEMULEN 1/50-21

AB + SEARLE

0.035MG; 1MG
0.05MG; 1MG

N18168 001
N16927 001

PRESCRIPTION DRUG PRODUCT LIST

3-231

NITROGLYCERIN

INJECTABLE; INJECTION

AP + NITRO-BID HOECHST MARION RSSL 5MG/ML

NITROGLYCERIN

AP + ABBOTT 5MG/ML

AP LUITPOLD 5MG/ML

AP SMITH AND NEPHEW 5MG/ML

AP NITROGLYCERIN IN DEXTROSE 5% 10MG/100ML

AP ABBOTT 0.1MG/ML

AP 20MG/100ML

AP 40MG/100ML

AP 10MG/100ML

AP + BAXTER HLTHCARE 20MG/100ML

AP + 40MG/100ML

AP + TRIDIL 5MG/ML

AP + FAULDING 0.5MG/ML

OINTMENT; TRANSDERMAL

NITROGLYCERIN 2%

ALTANA

NIZATIDINE

CAPSULE; ORAL

AXID 150MG

LILLY 300MG

+

NOREPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

LEVOPHED EQ 1MG BASE/ML

N18621 001 JAN 05, 1982 N07513 001

NOREPINEPHRINE BITARTRATE; PROCAINE HYDROCHLORIDE; PROPOXYCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

RAVOCAINE AND NOVOCAIN W/ LEVOPHED EQ 0.033MG BASE/ML; 2%;

0.4% N08592 003

NORETHINDRONE

TABLET; ORAL

NOR-QD 0.35MG

N17060 001

TABLET; ORAL-28

MICRONOR 0.35MG

N16954 001

NORETHINDRONE; *MULTIPLE*

SEE ETHINYL ESTRADIOL; NORETHINDRONE

SEE MESTRANOL; NORETHINDRONE

NORETHINDRONE ACETATE

TABLET; ORAL

AYGESTIN 5MG

N18405 001 APR 21, 1982

AB WYETH AYERST

AB NORLUTATE

AB + PARKE DAVIS 5MG

N12184 002

NORETHINDRONE ACETATE; *MULTIPLE*

SEE ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

N19508 001

APR 12, 1988

N19508 002

APR 12, 1988